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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,569	05/14/1998	WILLIAM J. BOYLE	A-451H	8492
21069	7590	06/15/2004	EXAMINER	
AMGEN INCORPORATED MAIL STOP 27-4-A ONE AMGEN CENTER DRIVE THOUSAND OAKS, CA 91320-1799			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/15/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/079,569

Applicant(s)

BOYLE, WILLIAM J.

Examiner

Emily Le

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/14/1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 12/14/1998 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/079569 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Miscellaneous***

2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

### ***Status of Claims***

3. Originally filed claims 1-21 and 25-33 were canceled by the previous Examiner of record, wherein authorization for the cancellation of the claims was given by Mr. Robert Winter, in a telephonic interview with Mr. Winter on September 14, 1998. Original claims 22-24 are pending in the instant application.

Claim 22: An antibody or fragment thereof which specifically binds an osteoprotegerin binding protein.

Claim 23. The antibody of claim 22 which is a monoclonal antibody.

Claim 24. A method for detecting the presence of an osteoprotegerin binding protein in a biological sample comprising: incubating the sample with the antibody of claim 22 under conditions that allow binding of the antibody to the osteoprotegerin binding protein; and detecting the bound antibody.

***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Specifically, Figure 2 and 3 do not show details that can be seen by the Examiner. Application is required to submit substituted drawings.

***Specification***

5. The abstract of the disclosure is objected to because it is not a concise statement of the technical disclosure of the claimed patent. Correction is required. See MPEP § 608.01(b). The instant claims encompass antibodies that binds to osteoprotegerin binding proteins, however, the abstract is not commensurate in scope with the claimed invention.

6. The disclosure is objected to because of the following informalities: the term "domain" is misspelled on line 36 of page 3 of the specification. Appropriate correction is required.

***Information Disclosure Statement***

7. The supplemental information disclosure statement (IDS) filed 12/1998 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other

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information or that portion which caused it to be listed; and 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. The IDS statement filed fails to comply with 37 CFR 1.98(a)(2), because neither the list nor the references are in the file wrapper of the instant application. Therefore, the IDS has been placed in the application file, but the information referred to therein has not been considered. The Examiner has only been able to locate the cover sheet for the submission of the IDS. The list of references and the actual references cannot be located. Application is required to re-submit the IDS, along with the list of references and the actual references if consideration is desired.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 22-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to an antibody that specifically binds an osteoprotegerin binding protein. Currently, as written, the claims read on a product of nature. The claims do not require the claimed antibody be isolated, which implies that the "hand-of-man" was involved. Therefore, because the claims read on a product of nature, the claims are directed to non-statutory subject matter under 35 U.S.C. 101.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method claim is rendered indefinite because the preamble of the method and the last method step within the claimed method do not parallel with one another. The preamble states that the claimed method is for the detection of an osteoprotegerin binding protein; yet, the last method step of the claimed method is directed to the detection of the bound antibody.

In addition, claim 24 recites the limitation "the bound antibody" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 22-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al. in U.S. Patent No. 6242586, filed 12/12/1997, see columns 14-15 of publication and sequence alignments. The priority date of Gorman et al. is 12/12/1997, see the cover page of the publication. Therefore, the teachings of Gorman et al. are available as prior art.

Gorman et al. teaches a protein that is identical to the osteoprotegerin binding protein that is taught in the instant specification. The protein of Gorman et al., identified as 499E9, has 100% sequence identity to that of the osteoprotegerin binding protein that is taught in the instant specification, SEQ ID NO: 7. Therefore, the protein taught by Gorman et al. is an osteoprotegerin binding protein. Gorman et al. also teaches monoclonal antibodies that specifically binds to an osteoprotegerin binding protein. Therefore, Gorman et al. anticipates the instantly claimed invention.

14. Claims 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamaguchi et al., U.S. PreGrant Publication No. 2003/0208045, see Examples 18 and 29-39 and sequence alignments. The priority date of Yamaguchi et al. is April 15, 1998, see the cover page of the publication. Therefore, the teachings of Yamaguchi et al. are available as prior art.

Yamaguchi et al. teaches an osteoprotegerin binding protein. Yamaguchi et al. also teaches monoclonal antibodies. Yamaguchi et al. teaches a monoclonal antibody

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that specifically binds to an osteoprotegerin binding protein. Therefore, the antibody taught by Yamaguchi et al. anticipates the instantly claimed invention.

Additionally, Yamaguchi et al. also teaches a method of detecting osteoprotegerin binding protein by incubating the antibody that specifically binds to osteoprotegerin binding protein with osteoprotegerin binding protein, and detecting the bound antibody. Therefore, Yamaguchi et al. anticipates the instantly claimed method.

### ***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



16. Claims 22-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 82-87 and 91-92 of copending Application No. 09/211,297. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims contain overlapping subject matter.

The claims of the instant application are directed to any antibody, humanized or non-humanized antibody that specifically binds to any osteoprotegerin binding protein.

The claims of the '297 application are directed to humanized antibodies that specifically binds to an epitope of an osteoprotegerin binding protein.

The scope of the instant claims encompasses humanized antibodies. Therefore, the instant claims anticipates the humanized antibodies of the '297 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 22-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/180,648. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims contain overlapping subject matter.

The claims of the instant application are directed to any antibody that specifically binds to any osteoprotegerin binding protein.

The claims of the '648 application are directed to an antibody. While the claims do not indicate that the antibody of the '648 application specifically binds to an

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osteoprotegerin binding protein, the specification teaches that the claimed antibody in the '648 application binds to an osteoprotegerin binding protein

The claims of the instant invention anticipates the antibody of the '648 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 22-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 and 54-73 of copending Application No. 10/408901. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims contain overlapping subject matter.

Claims 22-23 of the instant application are directed to any antibody and fragments thereof that specifically binds to any osteoprotegerin binding protein.

Claims 1-51 and 55-73 of the '901 application are directed to a human antibody that specifically binds to osteoprotegerin binding protein.

The scope of the instant claims encompasses humanized antibodies. Therefore, the instant claims anticipates the humanized antibodies of the '901 application.

Instant claim 24 is drawn to a method for detecting osteoprotegerin binding protein in a sample with the active method steps of incubating the sample with an antibody that specifically binds to an osteoprotegerin binding protein under conditions that allow for binding of the antibody to an osteoprotegerin binding protein, and detecting the bound antibody.

Claim 54 of the '901 application is also drawn to a method for detecting osteoprotegerin binding protein/ligand in a biological sample with the active method steps of contacting the sample with the antibody that binds to osteoprotegerin binding protein under conditions that allow for binding of the antibody to an osteoprotegerin binding protein, and measuring the level of bound antibody in the sample.

It would have been prima facie obvious for the skilled artisan in the art to measure the antibody that is detected with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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